

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

**THIS PAGE BLANK (USPTO)**

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



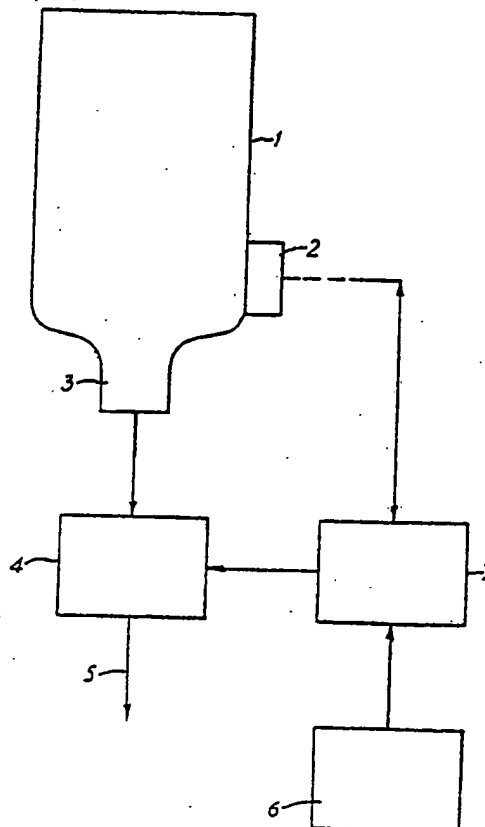
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification<sup>4</sup> :  A61M 5/14</p>	<p>A1</p>	<p>(11) International Publication Number: WO 85/ 00292  (43) International Publication Date: 31 January 1985 (31.01.85)</p>
<p>(21) International Application Number: PCT/GB84/00249 (22) International Filing Date: 10 July 1984 (10.07.84) (31) Priority Application Number: 8318670 (32) Priority Date: 11 July 1983 (11.07.83) (33) Priority Country: GB  (71) Applicant: IMPERIAL CHEMICAL INDUSTRIES PLC (GB/GB); Imperial Chemical House, Millbank, London SW1P 3JF (GB). (72) Inventors: COFFEE, Ronald, Alan ; BENNETT, Peter, Charles ; HOUGHTON, Leonard, Eric ; JOHNSON, Graham, Charles ; Verdley House, Fernhurst, Nr. Haslemere, Surrey GU27 3JE (GB). (74) Agent: MATHYS &amp; SQUIRE; 10 Fleet Street, London EC4Y 1AY (GB).</p>	<p>(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), JP, NL (European patent), SE (European patent).  Published With international search report.</p>	

(54) Title: FLUID DELIVERY APPARATUS

(57) Abstract

Apparatus for supplying a patient with a fluid from a container (1) having a memory device (2) associated therewith. The memory device contains information relating to the contents of the container, such as the nature of the contents and the volume remaining within the container. Means (6) are provided for monitoring a body parameter indicative of the patient's condition and further means are provided for storing information defining the rate of flow of various fluids required for various body conditions. A processor reads the information contained in the memory device and the stored information actuates a flow control device (4) associated with the container in accordance with signals supplied by the monitoring means.



**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ER	Republic of Korea
AU	Australia	LI	Liechtenstein
BE	Belgium	LK	Sri Lanka
BG	Bulgaria	LU	Luxembourg
BR	Brazil	MC	Monaco
CF	Central African Republic	MG	Madagascar
CG	Congo	MR	Mauritania
CH	Switzerland	MW	Malawi
CM	Cameroon	NL	Netherlands
DE	Germany, Federal Republic of	NO	Norway
DK	Denmark	RO	Romania
FI	Finland	SD	Sudan
FR	France	SE	Sweden
GA	Gabon	SN	Senegal
GB	United Kingdom	SU	Soviet Union
HU	Hungary	TD	Chad
JP	Japan	TG	Togo
KP	Democratic People's Republic of Korea	US	United States of America

FLUID DELIVERY APPARATUS

This invention relates to fluid delivery apparatus and in particular to apparatus for delivery of a fluid to a patient, eg. in the course of treatment. Examples of such fluids include blood, plasma, saline solutions, drug formulations, insulin, stimulants,  
5 and anaesthetics.

It is often desirable to control the flow of fluid to the patient in response to some parameter indicative of the patient's condition: examples of such parameters include respiration rate, pulse, blood pressure, brain activity, temperature, and the composition of a body fluid eg. exhaled breath, urine, or blood.  
10

However, there is often a risk of error; for example supply of the wrong fluid to the patient and/or supply of the wrong quantity of fluid and/or supply at the wrong rate. This risk may be compounded by possible variation in the nature of the fluid eg. differing blood groups, drug formulations of differing concentrations and the like.  
15

We have devised apparatus whereby such risks can be minimised.

Accordingly the present invention provides apparatus for supplying a patient with a fluid comprising means for monitoring a  
20 parameter indicative of the patient's body condition, a container having a memory device associated therewith, the memory device



- 2 -

containing information relating to the contents of the container, means for connection to said container for delivery of fluid from said container to the patient, flow control means for controlling the flow of fluid from said container to said patient, and means  
5 for reading the information stored in the memory device, whereby the flow control means can be operated in accordance with the read information and the signal derived from the monitoring means.

It is seen that an important feature of the invention is the provision of an information carrying memory device associated with,  
10 and preferably attached to, the container. This memory device is coded with information relating to the contents of the container. Such containers are described in our European Patent Application No. 83300035 (Publication No. 00086029), the disclosure of which is incorporated herein by reference.

15 The memory device is preferably an active electronic memory device, preferably digital, eg. a micro-chip, such as a PROM.

The flow control means may be a simple on/off valve or may be a proportional valve whose setting is determined by the monitored parameter in conjunction with the information carried by  
20 the memory device. The flow control means may be incorporated in the container or, alternatively, may be incorporated in the means for connection to the container for delivering the fluid to the patient.

The invention will now be described, by way of example,  
25 with reference to the accompanying drawings, in which:-

- 3 -

Figure 1 is a diagrammatic representation of an apparatus according to the invention; and

Figure 2 is an axial section of a container fitted with a memory device and a connector to the fluid delivery means.

5           In Figure 1 there is shown a container 1 having a memory device 2 associated therewith. The type of information that may be carried by the memory device 2 includes not only the precise nature of the fluid within the container 1, but also the optimum delivery rate for a given value of a relevant body parameter. Also a  
10 security code may be provided so that delivery of the fluid can only take place when the relevant body parameter is being monitored and has a value within a particular range. The memory device 2 may also carry information regarding the amount of fluid remaining within the container 1 so that a warning signal can be given when the container  
15 approaches exhaustion of its contents.

An outlet port 3 of container 1 is connected to a fluid flow control device 4 for delivering fluid to a patient (not shown) via a line 5. A monitor 6 is provided to monitor one or more relevant body parameters of the patient.

20           The memory device 2 is read by a control unit 7 which also receives signals from the monitor 6. The unit 7 contains a processor which operates in accordance with a program stored therein. Associated with the processor is a store for information defining the flow rates of various fluids required by patients according  
25 to age and other factors and according to the existing value of the body parameter, as monitored by the monitor 6.

- 4 -

In response to the information read from the memory device 2 indicating the precise nature of the fluid in container 1 and optimum delivery rates for any given value of a relevant monitored body parameter, the information stored in the processor of the unit 5 7, and the signals from monitor 6, the unit 7 supplies actuating signals to the fluid flow control device 4 to vary, as appropriate, the fluid delivered to the patient.

In Figure 2 the container 209 is shown inverted, having a cap 229 which is of a resilient plastic material which can sealingly 10 grip the edge 223 of the container opening. The cap is fitted with an outlet port 234 and a vent inlet 235. Inside the supply outlet 234 is a shaped sealed ring 236, formed of rubber or like material. A sealing plate 237 is urged against sealing ring 236 by compression spring 239 the other end of which abuts a circumferential flange 240 within the upper end of outlet 234. Secured inside the vent 15 inlet 235 and extending toward the upper end of the container 209 is an elongate duct 241, at the inner end of which is a spring-loaded ball valve 242, sealing the duct 241 against leakage of fluid from within container 209, but permitting air to enter container 209 when the pressure differential is sufficient to over- 20 come the spring-loading of ball valve 242. The cap 229 also carries a memory device in the form of a pre-coded microcircuit chip 214 mounted to communicate via external conductive socket connections 243. The outer edge of cap 229 carries a thread 247, and for transport and storage carries a protective threaded cap 25 lid (not shown).



- 5 -

The container 209 is mounted on the system via the connector 230, shown immediately below it. This comprises a cover member 244 formed with a flanged edge 245 supporting a freely rotatable threaded collar 246 which can engage with thread 247 to hold cover member 244 and cap 229 tightly together. Cover member 244 is formed with a projecting supply pipe 248 to mate with outlet 234, a projecting vent pipe 249 to mate with vent outlet 235 and female electrical contacts 251 to mate with male sockets 243. Connections 215 from contacts 251 lead to the memory reading device. Pipe 248 projects to a height sufficient so that, when cap 229 and cover 244 are in close contact, sealing plate 237 is lifted off sealing ring 236 so the fluid can flow out around the edges of plate 237 (which for this purpose are preferably partly cut away) into pipe 248.

It will be appreciated that the apparatus described with reference to Figure 1 can be modified by removing the store associated with the processor unit 7 and the connection between the unit 7 and the fluid control device 4. In this event, the unit 7 is provided with a display for information regarding the amount of fluid remaining in the container 1, derived from the memory device 2, and for the value of the body parameter, derived from the monitor 6. A doctor or nurse then manually adjusts the flow control device 6 in accordance with known information relating to the flow rate required and the patient's body condition.

- 6 -

CLAIMS

1. Apparatus for supplying a patient with a fluid comprising means for monitoring a parameter indicative of the patient's body condition, a container having a memory device associated therewith, the memory device containing information relating to the contents  
5 of the container, means for connection to said container for delivery of fluid from said container to the patient, flow control means for controlling the flow of fluid from said container to said patient, and means for reading the information stored in the memory device, whereby the flow control means can be operated in accordance  
10 with the read information and the signal derived from the monitoring means.
2. Apparatus as claimed in claim 1, further comprising means for storing information defining the flow rates required for various body conditions, the reading means being adapted further to read  
15 the information stored in the storage means and to actuate the flow control means in accordance with the information stored in the memory device and the storage means and the signal derived from the monitoring means.
3. Apparatus as claimed in claim 2, wherein the means for  
20 reading information and actuating the flow control means comprise a processing unit adapted to operate in accordance with a program stored in a memory thereof.
4. Apparatus as claimed in any one of the preceding claims,

- 7 -

wherein the information stored in the memory device comprises data representing the nature of the fluid within the container and the optimum delivery rate for a given value of the body parameter.

5. Apparatus as claimed in any one of the preceding claims,

5 wherein the information stored in the memory device comprises data forming a security code, whereby delivery of fluid is only allowed when the relevant body parameter is being monitored and has a value within a predetermined range.

6. Apparatus as claimed in any one of the preceding claims,

10 wherein the information stored in the memory device comprises information regarding the amount of fluid remaining within the container, whereby a warning signal is given when the container approaches exhaustion of the contents thereof.

7. Apparatus for supplying a patient with a fluid, the apparatus

15 being constructed, arranged and adapted to operate substantially as hereinbefore described with reference to, and as illustrated in, the accompanying drawings.

1/2

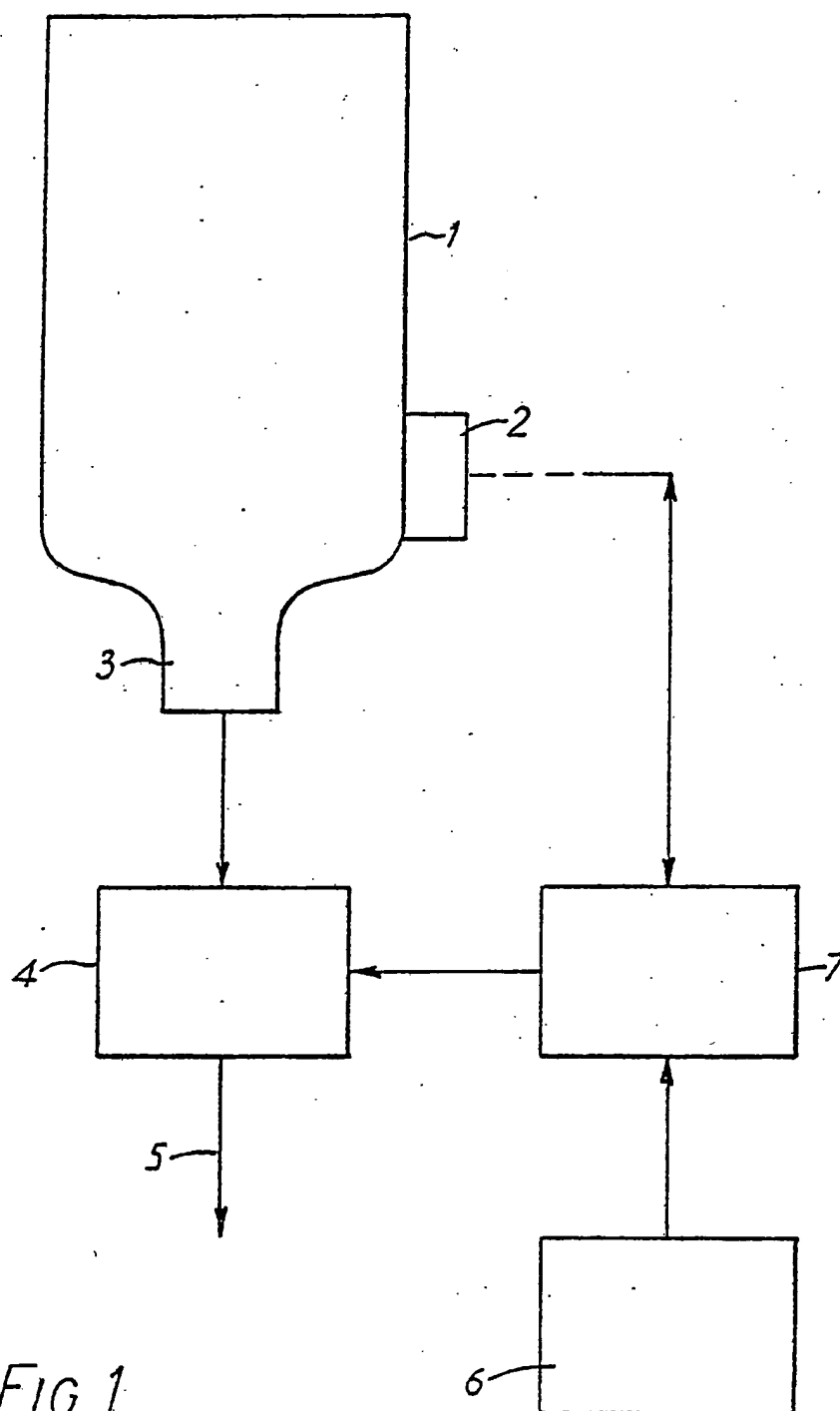


FIG. 1

2/2

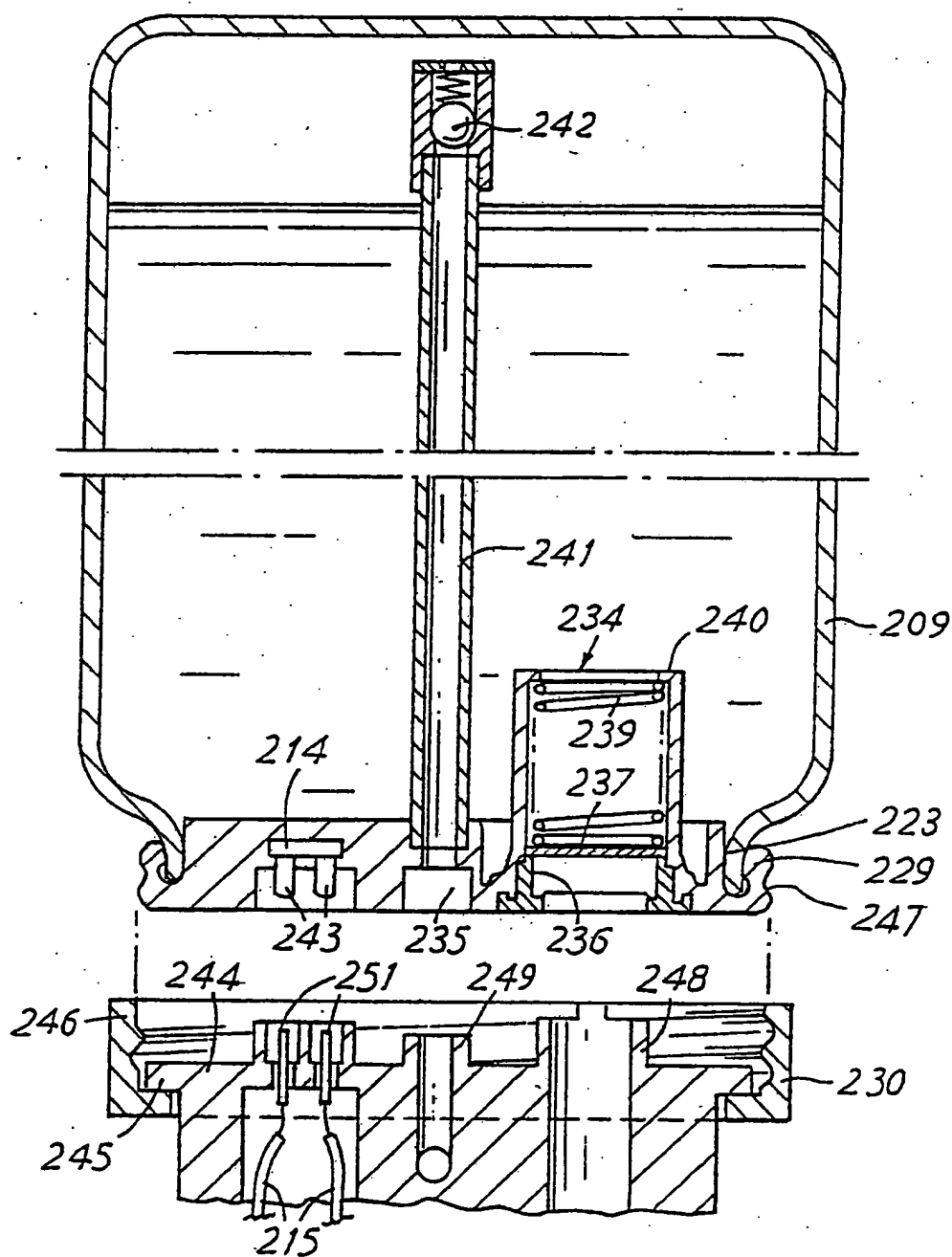


FIG. 2

SUBSTITUTE SHEET

# INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 84/00249

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (If several classification symbols apply, indicate all) <sup>2</sup> According to International Patent Classification (IPC) or to both National Classification and IPC IPC <sup>4</sup> :     A 61 M 5/14						
<b>II. FIELDS SEARCHED</b> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Minimum Documentation Searched <sup>4</sup></div> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; border-bottom: 1px solid black; padding: 5px;">Classification System</td> <td style="border-bottom: 1px solid black; padding: 5px;">Classification Symbols</td> </tr> <tr> <td style="padding: 5px;">IPC<sup>4</sup></td> <td style="padding: 5px;">A 61 M</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched <sup>4</sup></div>			Classification System	Classification Symbols	IPC <sup>4</sup>	A 61 M
Classification System	Classification Symbols					
IPC <sup>4</sup>	A 61 M					
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b> <sup>14</sup>						
Category <sup>5</sup>	Citation of Document, <sup>16</sup> with indication, where appropriate, of the relevant passages <sup>17</sup>	Relevant to Claim No. <sup>18</sup>				
Y	WO, A, 82/03554 (KAMEN) 28 October 1982 see page 3, lines 6-12; page 4, lines 17-22; page 5, lines 2-7; figures	1,2,3,6,7				
A	--	4,5				
Y	FR, A, 2350107 (MILES LABORATORIES) 2 December 1977 see page 3, line 27 - page 4, line 9; figure 1	1,2,3,6,7				
A	--	4,5				
A	BE, A, 832256 (BIOENGINEERING RESEARCH) 1 December 1975 see page 4, lines 1-11; figures	1-7				
A	US, A, 4078562 (FRIEDMAN) 14 March 1978 see column 2, lines 36-43; figure 1	1-5,7				
A	US, A, 4291692 (BOWMAN et al.) 29 September 1981 see column 3, lines 15-19; figures	1-5,7 ./.				
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><sup>15</sup> Special categories of cited documents: <sup>15</sup></p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"Δ" document member of the same patent family</p> </div> </div>						
<b>IV. CERTIFICATION</b>						
Date of the Actual Completion of the International Search <sup>3</sup> <div style="text-align: center; border: 1px solid black; padding: 5px; margin: 5px 0;">11th October 1984</div>	Date of Mailing of this International Search Report <sup>3</sup> <div style="text-align: center; border: 1px solid black; padding: 5px; margin: 5px 0;">06 NOV. 1984</div>					
International Searching Authority <sup>1</sup> EUROPEAN PATENT OFFICE	Signature of Authorized Officer <sup>10</sup> <div style="text-align: right; margin-top: 20px;">           G.L.M. J. J. J. J. J.       </div>					

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, <sup>16</sup> with indication, where appropriate, of the relevant passages <sup>17</sup>	Relevant to Claim No <sup>18</sup>
A	US, A, 3390238 (O'NEILL) 25 June 1968 see column 1, lines 9-15; figures	1,4
	---	
P,A	EP, A, 0086029 (IMPERIAL CHEMICAL INDUSTRIES) 17 August 1983 see figures 1 and 2; page 5, lines 1-6; page 6, lines 33-36 (cited in the application)	1,7
	---	
A	EP, A, 0058472 (IMPERIAL CHEMICAL INDUSTRIES) 25 August 1982 -----	

# ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO. PCT/GB 84/00249 (SA 7536)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 23/10/84

The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A- 8203554	28/10/82	EP-A- 0076840 US-A- 4411649	20/04/83 25/10/83
FR-A- 2350107	02/12/77	NL-A- 7704266 US-A- 4055175 DE-A, B 2720482 AU-A- 2394977 GB-A- 1547321 JP-A- 52135599 SE-A- 7705084	09/11/77 25/10/77 10/11/77 12/10/78 13/06/79 12/11/77 08/11/77
BE-A- 832256	01/12/75	None	
US-A- 4078562	14/03/78	None	
US-A- 4291692	29/09/81	None	
US-A- 3390238		None	
EP-A- 0086029	17/08/83	EP-A- 0086030 EP-A- 0086031 GB-A- 2115316 AU-A- 1034283 JP-A- 58146464 JP-A- 58146465 JP-A- 58150457	17/08/83 17/08/83 07/09/83 11/08/83 01/09/83 01/09/83 07/09/83
EP-A- 0058472	25/08/82	GB-A- 2093732 JP-A- 57159567 AU-A- 7994582 US-A- 4467961	08/09/82 01/10/82 19/08/82 28/08/84

For more details about this annex :  
see Official Journal of the European Patent Office, No. 12/82